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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|------------------------|----------------------|------------------|
| 10/670,454  | 09/26/2003  | Stephen Gregory Thomas | 0623.0970001/LBB/SJE | 5510             |
| 26111   | 7590        | 10/18/2006             | EXAMINER             |                  |
| STERNE, KESSLER, GOLDSTEIN & FOX PLLC<br>1100 NEW YORK AVENUE, N.W.<br>WASHINGTON, DC 20005 |             |                        | BAUM, STUART F       |                  |
|   |             |                        | ART UNIT             | PAPER NUMBER     |
|   |             |                        | 1638                 |                  |
| DATE MAILED: 10/18/2006   |             |                        |                      |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/670,454 | <b>Applicant(s)</b><br>THOMAS ET AL. |  |
|                              | <b>Examiner</b><br>Stuart F. Baum    | <b>Art Unit</b><br>1638              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006 and 03 August 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-35 and 37-45 is/are pending in the application.
- 4a) Of the above claim(s) 28-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-24, and 37-45 is/are rejected.
- 7) ☒ Claim(s) 25-27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/719,108.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. The amendments filed 7/13/2006 and 8/3/2006 have been entered.

2. Claims 22-35 and 37-45 are pending.

Claims 28-35 are withdrawn from consideration for being drawn to a non-elected invention.

Claims 1-21 and 36 have been canceled.

3. Claims 22-27 and 37-45 including SEQ ID NO:1 encoding SEQ ID NO:2 are examined in the present office action.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

6. This application contains claims 28-35 drawn to an invention nonelected with traverse filed 8/12/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Information Disclosure Statement***

7. Document JP 9000069 was not considered because an English language translation was not supplied. This objection is maintained for the reasons of record set forth in the Official action mailed 3/10/2006. Applicant's arguments filed 7/13/2006 have been fully considered but they are not persuasive.

Applicants contend MPEP §609.05(b) requires the Examiner to consider the foreign-language art insofar as it may be understood on its face (figures, formulas, etc) (page 9 of Remarks, top paragraph).

The Office contends that MPEP §609.05(b) also states “Each information disclosure statement must further include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information listed that is not in the English language.” Applicants are requested to submit said disclosure.

#### ***Written Description***

8. Claims 22-24 and 37-45 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/10/2006. Applicant’s arguments filed 7/13/2006 have been fully considered but they are not persuasive.

Applicants contend the specification describes the isolation of a GA 2-oxidase from *Phaseolus coccineus* whose sequence is set forth in SEQ ID NO:1 encoding SEQ ID NO:2, and which is called PcGA2ox1 (paragraph bridging pages 10 and 11 of Remarks). Applicants contend Example 3 describes the isolation of three GA 2-oxidases from *Arabidopsis thaliana*, AtGA2ox1, AtGA2ox2 and AtGA2ox3, using PcGA2ox1. Applicants contend subsequent to the filing date other GA 2-oxidases have been isolated from numerous plant species, and Applicants

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submit references describing said isolations as Exhibits A-E (*Ibid*). Applicants contend such disclosure conveys to those of ordinary skill in the art that Applicants had possession of the claimed invention (page 11 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend that because the GA 2-oxidase from *Phaseolus coccineus* was used to identify GA 2-oxidases from an unrelated plant species, they are in possession of GA 2-oxidase from *Phaseolus* (paragraph bridging pages 11 and 12 of Remarks).

The Office contends Applicants have broadly defined “GA 2-oxidase activity” to mean an enzyme capable of oxidizing C19-Gibberellin compounds by introduction of a hydroxyl group at C-2 $\beta$  (page 5 of specification, lines 4-6). Applicants disclose that the enzyme “may” also oxidize the 2 $\beta$ -hydroxyl group to a ketone group (page 5, lines 6-7). In addition, Applicants disclose that the four polypeptides, i.e., PcGA2ox1, AtGA2ox1, AtGA2ox2 and AtGA2ox3, have different substrate specificities and not all of the isolated GA 2-oxidases are capable of producing a GA-catabolite product (page 29, Table 1). Applicants state “The present invention shows that the enzyme from *P. coccineus* and two enzymes from *Arabidopsis thaliana* catalyse the 2 $\beta$ -hydroxylation of each substrate. In addition, the present invention shows that the *P. coccineus* enzyme and one of the *A. thaliana* enzymes form GA<sub>51</sub>-catabolite and CA<sub>34</sub> catabolite when incubated with GA<sub>9</sub> and GA<sub>4</sub>, respectively” (page 30, last paragraph). Therefore, not all isolated GA 2-oxidases from *Arabidopsis* have the same activity. Applicants have not disclosed a representative number of polynucleotides encoding a polypeptide with the same activity, or with the same substrate specificities. Applicants have also not disclosed essential elements of a GA 2-oxidase having a specific activity and substrate specificity. In regards to GA 2-oxidases

from *Phaseolus*, Applicants have not disclosed if there are other GA 2-oxidases from *Phaseolus* that have different activities or different substrate specificities.

Applicants contend that according to *Eli Lilly*, because Applicants have disclosed a GA 2-oxidase sequence from *Phaseolus coccineus*, and because Applicants have used this sequence to isolate other GA 2-oxidase sequences from another species of plant, therefore, they are in possession of the genus of *Phaseoleus* GA 2-oxidase (page 12 of Remarks, 1<sup>st</sup> full paragraph). Applicants contend that according to *Eli Lilly*, Applicants have provided common structural features and a sufficient number of representative species (page 12 of Remarks, bottom paragraph). Applicants contend a linear sequence is sufficient “structural features” for those of ordinary skill in the art (*Ibid*).

The Office contends that not all of Applicants’ cloned sequences have the same activity as discussed above. Disclosing a representative number of sequences encoding polypeptides with the same activity and substrate specificity is one way to fulfill the written description requirement. In the present application, the Office contends Applicants disclosed polypeptides, i.e., PcGA2ox1, AtGA2ox1, AtGA2ox2 and AtGA2ox3, do not all have the same activity and substrate specificity. In regards to GA 2-oxidases from *Phaseolus*, Applicants have not disclosed if there are other GA 2-oxidases from *Phaseolus* that have different activities or different substrate specificities.

Applicants contend that a single species was recently held to be sufficient to comply with the written description requirement. See *Invitrogen Corp v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005) (page 13 of Remarks, 1<sup>st</sup> full paragraph).

The Office contends that in *Invitrogen Corp v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005), at the time of the invention, sequences of RT genes were known, and that members of this gene family share significant homologies from one species to another. In the instant case, sequences of GA 2-oxidases were not known at the time the application was filed and therefore, a representative number of sequences encoding GA 2-oxidases all with the same activity and substrate specificity is required to fulfill the written description requirement, or a disclosure of essential elements that are required for a GA 2-oxidase, wherein all of the GA 2-oxidases have the same activity and substrate specificity.

#### *Scope of Enablement*

9. Claims 22-24 and 36-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant or plant cell transformed with a vector comprising SEQ ID NO:1 encoding SEQ ID NO:2, or a nucleic acid molecule encoding SEQ ID NO:2, wherein the nucleic acid molecule is operably linked to a promoter, wherein the transformed plant has a reduced height, and a delayed or absent inflorescence development which can be reversed by the application of GA<sub>3</sub>, does not reasonably provide enablement for a plant or plant cell comprising a vector comprising any nucleic acid encoding any protein having gibberellin 2-oxidase enzyme activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/10/2006. Applicant's arguments filed 7/13/2006 have been fully considered but they are not persuasive.

Applicants contend the specification need not disclose working examples for the invention to be enabled (paragraph bridging pages 13 and 14 of Remarks).

The Office contends that because of the state-of-the-art and unpredictability as recited in the office action mailed 3/10/2006, Applicants are required to supply a teaching of the invention either by disclosure or working example. The Office contends that Applicants have not supplied a sufficient teaching of the invention whereby one of skill in the art can make and/or use the broadly claimed invention.

Applicants contend the Biemelt reference teaches enablement of the invention because the present invention does not claim or make reference to lignin biosynthesis or biomass (paragraph bridging pages 14 and 15 of Remarks) and the Biemelt reference produced transgenic *Nicotiana sylvestris* dwarf plants (page 15 of Remarks, 2<sup>nd</sup> full paragraph).

The Office contends the Biemelt reference teaches unpredictability because the transgenic plants of Biemelt exhibit unexpected results in regards to normal plant development, which would also affect Applicants' claimed invention. The added unpredictability contributes to the undue trial and error experimentation that would be required by one of skill in the art.

Applicants contend the specification teaches cloning GA 2-oxidases (page 16 of Remarks, 2<sup>nd</sup> paragraph).

The Office contends that Applicants only teach prophetic examples of hybridization conditions that may work. Applicants do not disclose regions of any GA 2-oxidase, or regions of any *Phaseolus* GA 2-oxidase that could be used to generate primers or probes. Therefore, undue trial and error experimentation would be required by one of skill in the art, to screen through all the possible primers and probes for generating a nucleic acid sequence that encodes a GA 2-



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oxidase with an unspecified explicit activity and a specific substrate specificity, as discussed above.

Applicants contend that post-filing art is replete with evidence that GA 2-oxidases have been cloned from a wide variety of plants using the teachings of the present invention (page 16 of Remarks, 3<sup>rd</sup> paragraph).

The Office invites Applicants to point to specific locations within the supplied references where it is disclosed that post filing GA 2-oxidases were isolated using the teachings of the present invention.

10. Claims 22-27 and 37-45 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a plant cell or plant transformed with a vector comprising a nucleic acid which encodes a plant polypeptide having gibberellin 2-oxidase activity, or wherein the nucleic acid comprises SEQ ID NO:1 or comprises a nucleic acid encoding SEQ ID NO:2.

11. Claims 25-27 are objected to, but would be allowable if re-written in independent form including all the limitations recited in the claims from which they depend.

12. Claims 22-24, and 37-45 are not allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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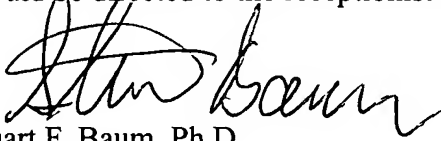
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with the first name "Stuart" and last name "Baum" clearly distinguishable.

Stuart F. Baum Ph.D.

Primary Examiner

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October 13, 2006